AUG 15 2003

510(K) SUMMARY

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

POWDER FREE NITRILE EXAMINATIN GLOVES (BLUE) WITH NATURAL WATER SOLUBLE VITAMIN E AND ALOE VERA, PEPPERMINT SCENTED

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990, and prepared on April 3,2003

The assigned 510(K) number is K031157

1.0 Submitter:

Qingdao Bestex Rubber & Plastic Products Co. Ltd.
14-2 Hangzhou Road,
Pingdu., Qingdao, China

2.0 Regulatory Affairs Contact:

Name: ZeChuan Shao
Phone No.: 408 980 1348
Fax No.: 408 980 1356

3.0 Name of device:

Trade Name: Undetermined
Common Name: Examination Glove
Classification Name: Patient Examination Glove, Powder Free

4.0 Identification of The Legally Marketed Device:

Class I nitrile patient examination gloves, 80LZA, non-sterile, powder free with natural water soluble Vitamin E and Aloe Vera, Peppermint Scented, that meets all the requirements of ASTM standard D 6319-00ae3 and FDA 21 CFR 800.20.

5.0 Device Description:

Class I powder free nitrile examination gloves (blue) with natural water soluble Vitamin E and Aloe vera, peppermint scented, 80LZA, non-sterile meets all the requirements of ASTM standard D6319-00ae3 and FDA 21 CFR 800.20.

6.0 Intended Use of The Device:

The powder free nitrile examination glove (blue) with natural water soluble Vitamin E and Aloe vera, peppermint scented, is a disposable device intended for medical purposes that are worn on the examiner's hands or fingers to provide a barrier against potentially infectious materials and other contaminants.

K031157

7.0 Summary of the Technological Characteristics of the Device:

The Powder Free Nitrile Examination Gloves (blue) with natural water soluble Vitamin E and Aloe Vera, Peppermint Scented, are summarized with the following technological characteristics compared to ASTM or equivalent standards:

Characteristics	Standards	Device Performance
Dimensions	ASTM D 6319-00ae3	Meets
Physical Properties	ASTM D 6319-00ae3	Meets
Freedom from Pinholes	ASTM D 6319-00ae3 FDA 21 CFR 800.20	Meets Meets
Powder Residue	ASTM D 6124-01	Meets, <2 mg/glove
Biocompatibility	Primary Skin Irritation In Rabbits	Passes
	Dermal Sensitization	Passes

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The standards used by Bestex Rubber & Plastic Products Co., Ltd. to determine substantial equivalence are based on ASTM 6319-00ae3 AND FDA 21 CFR 800.20. All testing meets requirements for physical specifications and dimensions conducted on gloves, Inspection level S-2, AQL 4.0, Pinholes at AQL 1.5

Primary Skin Irritation and Skin Sensitization testing were also conducted with results meets all performance and biocompatibility requirements.

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

No new clinical test were conducted under this 510(K)

10.0 Other Information Deemed Necessary by FDA:

Not applicable.

Conclusion

The data presented indicate that the Powder Free Nitrile Examination Glove with water soluble natural Vitamin E and Aloe Vera, Peppermint Scented (blue) meets ASTM standards, meet FDA pinhole requirements , biocompatibility requirements, and labeling claims. Consequently, this device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2003

Qingdao Bestex Rubber & Plastic Products Company Limited
C/O Mr. Zechuan Shao
Regulatory Affairs
2576 Lafayette Street
Santa Clara, California 95050

Re: K031157
Trade/Device Name: Powder-Free Nitrile Examination Glove (Blue) With Natural Water Soluble Vitamin E and Alove Vera, Peppermint Scented
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: July 2, 2003
Received: August 4, 2003

Dear Mr. Shao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031157

Qingdao Bestex Rubber & Plastic Products Co., Ltd.
Add: 14-2, Hangzhou Road, Pingdu, Qingdao, China Tel: 0086 532 8333339 Fax: 0086 532 8312027

3.0 Indications for Use Statement:

INDICATIONS FOR USE

Applicant: Qingdao Bestex Rubber & Plastic Products Co., Ltd.
510(k) Number(if known): *
Device Name: Powder-free nitrile examination glove (blue) with natural water soluble Vitamin E and Alove Vera, Peppermint scented

Indications For Use:

The Powder Free Nitrile Examination Glove (blue) with natural water soluble Vitamin E and Aloe Vera, Peppermint scented is a disposable device intended for medical purpose that is worn on the examiner's hand or finger(s)to prevent contamination between patient and examiner.

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Concurrence of CDRH Office of Device Evaluation(ODE)

Prescription Use_____ OR Over-The-Counter _____
Per 21 CFR 801.109 (Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031157